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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,455

09/12/2003

Thanyaphong Na Nakorn

STAN-278

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06/21/2006

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/661,455

Applicant(s)

NAKORN ET AL.

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 6, 9, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/28/04, 5/21/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The reply received 2/9/06 amending claim 7 and canceling claims 10, 11, and 14 is acknowledged. Claims 1-9, 12, and 13 are currently pending. It is noted that claims 8, 9, 12, and 13 are marked "withdrawn," but applicant is reminded that only the examiner can withdraw a claim in response to a restriction requirement. See M.P.E.P. § 821.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-6, in the reply filed on 2/9/06 is acknowledged. The traversal is on the ground(s) that the claims of Group II have been amended such that they are commensurate in scope with those of Group I. Applicants also requests rejoinder of Group IV under *Ochiai* practice. These arguments are persuasive in part. Claims 7-9 are rejoined to Group I. The requirement for restriction between Group I and Group II is withdrawn. Group IV will not be rejoined to Group I at this time, however, since the product claim is not allowable.

The requirement between Group I and Groups III-V is still deemed proper and is therefore made FINAL. Claims 12 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/9/06.

Applicant's election of various species, including "cells comprising no exogenous DNA vector" and "bone marrow," in the reply filed on 2/9/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse

(MPEP § 818.03(a)). Claims 6 and 9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/9/06.

Examination will commence at this time on claims 1-5, 7, and 8, to the extent that they read on the elected species where appropriate.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because it is not clear whether the claim requires 80% of the cells to express all of CD41, CD9, and CD34 or whether 80% of the cells must express any one of CD41, CD9, and CD34. Clarification is required. In light of the examples, the examiner suggests that the claim be amended to recite, "wherein at least 80% of the cells express CD41, CD9, and CD34."

Because claims 2-5 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 2 requires that the cells be "characterized as lineage panel-," which is confusing for several reasons. First, as discussed above, the claim is drawn to a composition, but it appears to recite an active method step, as discussed above regarding claim 1. Furthermore, the term "lineage panel" is not particularly defined

within the claim, and the specification provides numerous contradictory definitions. At paragraph 26, the specification allows that lineage markers “may include” a particular list of markers; paragraph 38, however, defines a lineage panel as comprising a totally different set of markers. Clarification is required. The examiner suggests that the limitations of claim 3 be incorporated into claim 2 and that claim 2 be amended to recite, “wherein said cells do not express CD2, CD3...and glycophorin A.”

Claim 4 requires that the cells be cultured “in the presence of” a particular agent, which does not necessarily require that the agent physically interact with the cells. It is suggested that “in the presence of” be replaced with “with.” Clarification is required.

Claim 7 recites “cells that are [characterized as] CD41<sup>+</sup>, CD9<sup>+</sup>, CD34<sup>+</sup>” at lines 3 and 6, but as discussed above, it is not clear whether the each and every cell must express all three markers, or whether cells expressing only one would be encompassed by the claim. Clarification is required. The examiner suggests that this phrase be amended to recite, “cells that express CD41, CD9, and CD34.”

Because claim 8 depends from indefinite claim 7 and does not clarify the point of confusion, it must also be rejected under 35 U.S.C. 112, second paragraph.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Clay et al. (2001, *Blood* 97: 1982-1989; reference U). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not the markers within a lineage panel. The claims are also drawn to a method of enriching a cell population for cells that express CD41, CD9, and CD34 comprising contacting a sample of hematopoietic cells with reagents that recognize CD41, CD9, and CD34 and selecting for cells that express CD41, CD9, and CD34. In some dependent claims, the sample of hematopoietic cells is bone marrow.

Clay et al. teach a purified population of cells that express CD41, CD9, and CD34 (Figure 2; page 1985, column 2). These cells were purified using immunomagnetic bead sorting, which comprises contacting human bone marrow mononuclear cells with a hapten-conjugated anti-CD34 antibody and anti-hapten antibody-coated magnetic beads, which yielded a >97% pure population of CD34+ cells (page 1983, column 1, paragraph 3). These purified CD34+ cells were further contacted with anti-CD9 antibodies and anti-CD41 antibodies and sorted to near purity using a flow cytometer (page 1983, column 1, paragraph 5; Figure 3). The population collected by gate E in Figure 3 is CD34+ CD9<sup>high</sup> CD41<sup>high</sup>; the population collected by gate D in Figure 3 is CD34+ CD9<sup>mid</sup> CD41<sup>mid/low</sup> (page 1985, column 2, paragraph 1). Clay et al. further teach that adding erythropoietin (EPO) to these cells gives rise to BFU-E/MK,

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megakaryocyte colonies (page 1985, column 2, paragraphs 2-3); the cells of Clay et al. are therefore mammalian megakaryocyte precursor cells. Clay et al. anticipates claim 2 because, as discussed above in the rejections under section 112, second paragraph, "lineage panel" is not particularly defined; the cells of Clay et al. do not express CD7 and CD38, for example (page 1985, column 1, paragraph 2), so they are lineage panel when "lineage panel" is defined as, for example, "expressing CD7 and CD38."

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Clay et al. (reference U). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not other particular markers. In some dependent claims, the cells have various properties when cultured under particular conditions. The claims are also drawn to a method of enriching a cell population for cells that express CD41, CD9, and CD34 comprising contacting a sample of hematopoietic cells with reagents that recognize CD41, CD9, and CD34 and selecting for cells that express CD41, CD9, and CD34. In some dependent claims, the sample of hematopoietic cells is bone marrow.

As discussed above, Clay et al. teach a purified population of cells that express CD41, CD9, and CD34 (Figure 2; page 1985, column 2). These cells were purified using immunomagnetic bead sorting, which comprises contacting human bone marrow mononuclear cells with a hapten-conjugated anti-CD34 antibody and anti-hapten antibody-coated magnetic beads, which yielded a >97% pure population of CD34+ cells (page 1983, column 1, paragraph 3). These purified CD34+ cells were further contacted

with anti-CD9 antibodies and anti-CD41 antibodies and sorted to near purity using a flow cytometer (page 1983, column 1, paragraph 5; Figure 3). The population collected by gate E in Figure 3 is CD34<sup>+</sup> CD9<sup>high</sup> CD41<sup>high</sup>; the population collected by gate D in Figure 3 is CD34<sup>+</sup> CD9<sup>mid</sup> CD41<sup>mid/low</sup> (page 1985, column 2, paragraph 1). Clay et al. further teach that adding erythropoietin (EPO) to these cells gives rise to BFU-E/MK, megakaryocyte colonies (page 1985, column 2, paragraphs 2-3); the cells of Clay et al. are therefore mammalian megakaryocyte precursor cells.

Regarding the limitations of claims 3 and 4, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the cell population discussed in Clay et al. Accordingly, it has been established that the prior art cell population, which expresses CD41, CD9, and CD34 and has the ability to differentiate to megakaryocyte colonies when treated with EPO, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The fact that a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The instantly claimed cell population possesses inherent characteristics, for example the lack of expression of the markers recited in claim 3 and the response to the agents recited in claim 4, which might not be displayed in the tests used by Clay et al. Clear substantive evidence (and not merely attorney argument) that the cell population of the cited prior art does not



possess a critical characteristic that is possessed by the claimed cell population would advance prosecution and might permit allowance of claims to applicants' cell population.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Akashi et al. (2000, *Nature* 404: 193-197; cited on IDS of 1/28/04). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not other particular markers. In some dependent claims, the cells have various properties when cultured under particular conditions. In some dependent claims, the cells are mouse cells.

Akashi et al. teach an essentially pure population of mouse bone marrow cells that express CD34 and do not express CD3, CD4, CD8, or CD19 (the "FcγR<sup>lo</sup> CD34<sup>+</sup> cells;" Figure 1b; page 196, column 2, paragraph 3). The FcγR<sup>lo</sup> CD34<sup>+</sup> cells of Akashi et al. give rise to megakaryocytes when cultured in methylcellulose with steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF, thrombopoietin, and erythropoietin (page 193, column 2, paragraph 3; Figure 2) the FcγR<sup>lo</sup> CD34<sup>+</sup> cells of Akashi et al. are therefore mammalian megakaryocyte progenitor cells.

Regarding the limitations of claims 1 and 3, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the cell population discussed in Akashi et al. Accordingly, it has been established that the prior art cell population, which expresses CD34 and has the ability to differentiate to megakaryocyte

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colonies when cultured in methylcellulose with steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF, thrombopoietin, and erythropoietin, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The fact that a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The instantly claimed cell population possesses inherent characteristics, for example the lack of expression of all the markers recited in claim 3, the expression of CD9 and CD41 as in claim 1, and the ability to form megakaryocyte colonies *in vitro* as recited in claim 4, which might not be displayed in the tests used by Akashi et al. Clear substantive evidence (and not merely attorney argument) that the cell population of the cited prior art does not possess a critical characteristic that is possessed by the claimed cell population would advance prosecution and might permit allowance of claims to applicants' cell population.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Na Nakorn et al. (2002, *Journal of Clinical Investigation* 109: 1579-1585; cited on IDS of 1/28/04). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not other particular markers. In some dependent claims, the cells have various properties when cultured under particular conditions. In some dependent claims, the cells are mouse cells.

Na Nakorn et al. teach an essentially pure population of mouse bone marrow cells that express CD34 and do not express CD3, CD4, CD8, or CD19 (the "FcγR<sup>lo</sup> CD34<sup>+</sup> cells;" Figure 1a; page 1580, column 1, paragraph 4). The FcγR<sup>lo</sup> CD34<sup>+</sup> cells of Na Nakorn et al. give rise to megakaryocytes when transplanted into mouse tibias (Figure 2b; page 1581, column 2, paragraph 1); the FcγR<sup>lo</sup> CD34<sup>+</sup> cells of Na Nakorn et al. are therefore mammalian megakaryocyte progenitor cells.

Regarding the limitations of claims 1, 3, and 4, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the cell population discussed in Na Nakorn et al. Accordingly, it has been established that the prior art cell population, which expresses CD34 and has the ability to differentiate to megakaryocyte colonies, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The fact that a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The instantly claimed cell population possesses inherent characteristics, for example the lack of expression of all the markers recited in claim 3, the expression of CD9 and CD41 as in claim 1, and the ability to form megakaryocyte colonies *in vitro* as recited in claim 4, which might not be displayed in the tests used by Na Nakorn et al. Clear substantive evidence (and not merely attorney argument) that the cell population of the cited prior art does not possess

a critical characteristic that is possessed by the claimed cell population would advance prosecution and might permit allowance of claims to applicants' cell population.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weissman et al. (2002, U.S. Patent 6,465,247; IDS of 1/28/04; hereafter "Weissman et al. (I)"). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not other particular markers. In some dependent claims, the cells have various properties when cultured under particular conditions. In some dependent claims, the cells are mouse cells.

The applied reference has a common current assignee and shares one inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Weissman et al. (I) teach an essentially pure population of mouse bone marrow cells that express CD34 and do not express CD3, CD4, or CD8 (the "FcγR<sup>lo</sup> CD34<sup>+</sup> cells;" Example 1; column 13, lines 24-65; column 6, lines 7-9; and column 4, lines 24-25). The FcγR<sup>lo</sup> CD34<sup>+</sup> cells of Weissman et al. (I) give rise to megakaryocytes when cultured with a cocktail of steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF,

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thrombopoietin, and erythropoietin (column 4, lines 28-36; column 13, lines 45-54); the  $\text{Fc}\gamma\text{R}^{\text{lo}}$   $\text{CD34}^+$  cells of Weissman et al. (I) are therefore mammalian megakaryocyte progenitor cells.

Regarding the limitations of claims 1 and 3, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the cell population discussed in Weissman et al. (I). Accordingly, it has been established that the prior art cell population, which expresses CD34 and has the ability to differentiate to megakaryocyte colonies when treated with steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF, thrombopoietin, and erythropoietin, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The fact that a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The instantly claimed cell population possesses inherent characteristics, for example the lack of expression of all the markers recited in claim 3 and the expression of CD9 and CD41, which might not be displayed in the tests used by Weissman et al. (I). Clear substantive evidence (and not merely attorney argument) that the cell population of the cited prior art does not possess a critical characteristic that is possessed by the claimed cell population would advance prosecution and might permit allowance of claims to applicants' cell population.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Weissman et al. (2002, U.S. Patent Application Publication 2002/0086422; IDS of 5/21/04; hereafter "Weissman et al. (II)"). The claims have been interpreted as being drawn to a composition comprising cells that express CD41, CD9, and CD34, but not other particular markers. In some dependent claims, the cells have various properties when cultured under particular conditions. In some dependent claims, the cells are mouse cells.

The applied reference has a common current assignee and shares two inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Weissman et al. (II) teach an essentially pure population of mouse bone marrow cells that express CD34 and do not express CD2, CD3, CD4, CD8, CD19, IgM, Ter110, and Gr-1 and two populations of human bone marrow cells that express CD34 and do not express CD2, CD3, CD4, CD7, CD8, CD10, CD11b, CD14, CD19, CD20, CD56, and glycophorin A (the "FcγR<sup>lo</sup> CD34<sup>+</sup> cells" in mice; the "lin<sup>-</sup> CD34<sup>+</sup> CD38<sup>+</sup> IL-3Rα<sup>lo</sup> CD45RA<sup>-</sup> fraction" or "CMP" and the "CD34<sup>+</sup> CD38<sup>+</sup> IL-3Rα<sup>-</sup> CD45RA<sup>-</sup> fraction" or "MEP" in humans; Examples 1 and 2; paragraphs 0023, 0078, and 0096). The FcγR<sup>lo</sup> CD34<sup>+</sup> mouse cells, the human CMP, and the human MEP of Weissman et al. (II) all

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give rise to megakaryocytes when cultured with a cocktail of steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF, thrombopoietin, and erythropoietin (paragraphs 0079 and 0096); the cells and fractions of Weissman et al. (II) are therefore mammalian megakaryocyte progenitor cells.

Regarding the limitations of claims 1 and 3, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' cell population differs, and if so to what extent, from the cell population discussed in Weissman et al. (II). Accordingly, it has been established that the prior art cell populations, which express CD34, do not express various other markers, and have the ability to differentiate to megakaryocyte colonies when treated with steel factor, flt-3 ligand, interleukin-3, interleukin-11, GM-CSF, thrombopoietin, and erythropoietin, demonstrate a reasonable probability that they are either identical to the claimed cell population or sufficiently similar to the claimed cell population that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

The fact that a characteristic of a known cell population is not disclosed in a reference does not make the known cell population patentable. The instantly claimed cell population possesses inherent characteristics, for example the lack of expression of all the markers recited in claim 3 and the expression of CD9 and CD41, which might not be displayed in the tests used by Weissman et al. (II). Clear substantive evidence (and not merely attorney argument) that the cell population of the cited prior art does not

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possess a critical characteristic that is possessed by the claimed cell population would advance prosecution and might permit allowance of claims to applicants' cell population.

***Conclusion***

Applicant should specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



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